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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/721,702
Filing Date: November 25, 2003
Appellant(s): STINSON, JONATHAN S.

John S. Sopko
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/11/2008 appealing from the Office action mailed 02/20/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief. However, application 09/556671 is unrelated to this application and has a different party of interest.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because the summary is not concise and adds unclaimed disclosure to the explanation

(namely, comparisons to metal stents and a negative limitation "without the use of other stent structures").

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5500013	Buscemi et al	3-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30, 44, 46, 50-59 and 76-84 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buscemi et al (US 5500013).

Buscemi et al discloses a bioabsorbable endoprosthesis (18) consisting essentially of (the same as comprising in the broadest reasonable interpretation of the claims): at least one elongate element (18) having an outer surface, the element including a bioabsorbable polymer (poly-l-lactide, col 4, line 56) adapted to undergo degradation in vivo (col 4, line 55), the element including an elongate, axially extending reservoir portion (hollow, col 4, line 47) adapted (i.e. in as much as the present invention, since the structure is the same) and fully capable of collecting a by-product of the degradation of the bioabsorbable polymer (i.e. since it is hollow, by-products "may at least partially collect", such as disclosed by the applicant); wherein the at least one element (18) occupies a total element volume including a reservoir volume (hollow space) occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume (col 4, lines 60-67, .2 mm fiber with a .025 to .1 mm wall is 0-56.25% which encompasses about 10-40%) .

With regard to claim 51, the at least one elongate element is formed into a tubular, radially expandable structure (such as figs. 1 and 3).

With regard to claims 52 and 54, the at least one elongate element (18) comprises a first plurality of elements helically wound (braided, col 4, line 43) about an axis in a first direction, and a second plurality of elements helically wound about the axis in a second direction opposite the first direction to form multiple crossings with the first plurality of the elements (i.e. at any point along a braid there will be "an axis" and the three or more elements required to make a braid helically wind as claimed).

With regard to claim 53, Buscemi et al remains silent as to the specific crossing angles of the braid ranging from about 120 degrees to about 150 degrees. Applicant has not

disclosed that having the crossings extending at this range of angles solves any stated problem or is for any particular purpose. Moreover, it appears that the endoprosthesis would perform equally well with the crossings at angle of braid. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify (if not inherently encompassed by a braid) the braid of Buscemi et al such that the cross over angle ranges are from about 120 degrees to about 150 degrees because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Buscemi et al.

With regard to claims 55-56, PLLA a polylactide polymer is disclosed (col 4, line 56)

With regard to claim 57, polyglycolide, an others and their combinations are disclosed as suitable biodegradable materials (col 6, lines 11-20).

With regard to claims 76-78, the examiner counts over 36 filaments in fig. 1 (approximately 48). However, Applicant has not disclosed that having a specific number of filaments solves any stated problem or is for any particular purpose. Additionally, a length change is within the skill level on one of ordinary skill in the art. Moreover, it appears that the endoprosthesis would perform equally well with 10-36 filaments and/or a length of 0.25-0.75 the shown length. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Buscemi et al such that it has from 10-36 filament or 0.25-0.75 the length as shown because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Buscemi et al.

With regard to claim 79, Buscemi et al discloses an outward spring force but remains silent as to any specific range of force (namely 40-300 grams). Applicant has not disclosed that having a specific forces range of about 40-300 grams solves any stated problem or is for any particular purpose. Moreover, it appears that the endoprosthesis would perform equally well with any force positive range up to the vessels tolerance when fully expanded. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Buscemi et al such that it outward spring force was about 40-300 grams because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Buscemi et al.

With regard to claims 80-81, Buscemi et al includes overlapping ranges with the formula of the claims, which is considered prima facie obvious.

With regard to claims 82-84, Buscemi et al discloses braided, hollow (col 4, lines 41-49 and 60-68) and is a tubular, radially expandable structure as claimed. The formulas are discussed above regarding claims 76-78 and 80-81.

(10) Response to Argument

The arguments boil down to the interpretation of "consisting essentially of". In the absence of a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." Additionally, Applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of *Applicant's* invention rather than showing how the additional components materially change the rejecting reference. Applicant's invention clearly can include an inner "cover". The specification on page

18 notes that other known structures and feathers which enhance and cooperate with the structure are allowed (see the passage below). Buscemi et al is another stent functioning as a stent therefore it is doesn't materially effect its function. "However, it is known that other structures and features can be included in stents, and in particular features which enhance or cooperate with the tubular and self-expandable structure or which facilitate the implantation of the structure. One example is the inclusion of radiopaque markers on the structure which are used to visualize the position of the stent through fluoroscopy during implantation. Another example is the inclusion of a covering or additional interwoven filaments, for instance, to reduce the porosity or open spaces in the structure so that the stent can be used to prevent tissue ingrowth or be used as a grail. Other examples include collapsing threads or other structures to facilitate repositioning and removal of the stent. Stents of these-types nonetheless still substantially consist of the tubular and self-expandable structure formed by interwoven filaments 20, 30, 40." Regarding claims 81 and 82, fig. 3 shown 48 filaments, if cut at 14 or 20, if not cut which meets the range of 10-36. The diameter is 1-50 mm includes 6 mm which corresponds to 20 filaments (6/(.022(6)=.17)=20) meeting the number of filaments and thickness of .2 mm (6/(1.8(6)=15)-0.3= .2) as also disclosed by Buscemi et al. Variations on filament number and thickness are still a matter of design choice. Clearly the braid configuration would differ from fig. 1 and engineering choices are made based on optimizing various features including strength so it is obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Thomas J Sweet/

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/Thomas Barrett/

TQAS TC3700